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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BINGHAM, MCCUTCHEN LLP
THREE EMBARCADERO CENTER
18 FLOOR
SAN FRANCISCO, CA 94111-4067

EXAMINER	
ARTMAN, THOMAS R	

ART UNIT	PAPER NUMBER
2882	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,477	TAKAI ET AL.	
	Examiner	Art Unit	
	Thomas R. Artman	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-20,34,37-40,51,53-56 and 60-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-20,34,37-40,51,53-56 and 60-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Allowable Subject Matter

Upon further consideration, the previously-indicated allowable subject matter of claim 64 is in fact anticipated by Kunieda, previously made of record. Therefore, the indicated allowable subject matter of claim 64 is being withdrawn, as reflected in the following rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7, 9, 10, 12-15, 17-19, 51, 53, 54, 56 and 61-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Kunieda (US 6,307,914 B1).

Regarding claims 1 and 10, Kunieda discloses an apparatus and method for irradiating a target (Figs. 1 and 18-20), including:

a) establishing a relationship between at least one marker 14 relative to the target (tumor, not referenced in the figures) by measuring a relative position between the at least one marker and the target (col.12, lines 24-42),

b) generating an image signal of the at least one marker,

c) generating a tracking signal in response to the image signal, and

d) adjusting a radiation beam in response to the tracking signal for tracking the target (col.3, lines 14-37), and

e) the target is tracked, as indicated above, while performing IMRT using a first multileaf collimator 15a (col.16, line 33) in which a leaf of the first MLC is adjusted such that a first portion of the target receives more radiation than a second portion of the target.

With respect to claim 2, Kunieda further discloses the practice of generating an X-ray image of the marker, and the step of generating a tracking signal includes generating the tracking signal to track a movement of the target (col.3, lines 14-37).

With respect to claim 3, Kunieda further discloses the practice of generating the image signal regarding an anatomy of a patient having a tumor as the target (col.3, lines 14-37).

With respect to claims 4, 5, 53 and 54, Kunieda further discloses the practice of

a) illuminating the target and the area near the target with first and second image beams, where the beams are not parallel to each other, and

b) detecting first and second images, respectively, of the marker (col.3, lines 14-37).

With respect to claim 7, Kunieda further discloses the practice of adjusting the radiation beam using a first multileaf collimator 15a (col.4, lines 6-11; col.16, lines 13-37).

With respect to claim 9, Kunieda further discloses the practice of temporarily shutting off the beam in response to the tracking signal having a value indicating the target being outside an area (col.9, lines 20-28; col.12, lines 47-63).

Regarding claim 12, Kunieda discloses an apparatus for irradiating a target (Figs. 1 and 18-20), including:

a) a platform 20 for supporting an object having a marker 17 indicating a position of the target,

b) a radiation source generating a radiation beam 16 toward the platform,

c) a beam adjuster 15a between the radiation source and the platform, where the adjuster is a multileaf collimator,

d) a first image detector 21d,e generating a first image signal of the marker,

e) a control module (Fig.20) coupled to the image detector and to the beam adjuster, where the control module generates a beam adjustment signal for controlling the first multileaf collimator to track a movement of the target in response to the first image signal (col.4, lines 6-11), and

f) the control module is configured to control the first multileaf collimator 15a to perform IMRT, in which a leaf of the first MLC is adjusted such that a first portion of the target receives more radiation than a second portion of the target (col.16, line 33).

With respect to claim 13, Kunieda further discloses that the control module is coupled to the platform and generates a control signal to move the platform in response to the first image signal (Fig.19; col.3, line 66 through col.4, line 5; col.15, line 57 through col.16, line 11).

With respect to claim 14, Kunieda further discloses that the first image detector is a video camera (Fig.24) or an X-ray imager (Figs. 1, 19 and 20).

With respsect to claim 15, Kunieda further discloses that a gantry houses the radiation source and the beam adjuster (Fig.20).

With respect to claim 17, Kunieda further discloses a first image beam source 21a,b generating a first image beam toward the platform 20, where the first image detector 21d,e generates a first image signal by detecting the first image beam (Figs.19-20).

With respect to claim 18, Kunieda further discloses a second image beam source 22a,b that generates a second image beam toward the platform in a direction that is not parallel to the first image beam, and a second image detector 22d,e coupled to the control module, where the second image detector generates a second image signal by detecting the second image beam (Figs.19 and 20).

With respect to claims 19 and 56, Kunieda further discloses that the first image adjuster is a first multileaf collimator, which as is known in the art, has first and second rows of movable leaves opposite to each other.

With respect to claim 51, Kunieda further discloses that the target is located beyond a head region of a patient (see Figs.)

Regarding claim 64, Kunieda discloses a method for irradiating a target, comprising:

a) determining a position of the target (col.3, lines 14-34),

b) tracking the target based on the determined position (col.3, lines 35-37), and

c) delivering radiation to perform an intensity modulated radiation therapy on the target while the target is being tracked, where

d) the target is tracked by adjusting one or more leaves of a MLC 15a (col.16, lines 28-32), and where the radiation is delivered by further adjusting one of the one or more leaves of the MLC to modulate an intensity of the radiation delivered to the target such that a first region of the target receives more radiation than a second region of the target (col.16, lines 33-35).

With respect to claim 61, the target is tracked using a marker 14 placed on a patient (Fig.24).

With respect to claim 62, the target is tracked using a marker 17, 14 planted within the patient.

With respect to claim 63, the position is determined using a camera (21e, 22e; also see Fig.24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 6 and 55 are rejected under 35 U.S.C. 103(s) as being obvious over Kunieda, as applied to claims 1 and 10 above, in view of Kanematsu (US 6,385,288 B1).

Regarding both claims, Kunieda does not specifically disclose the practice of superimposing the tracking signal on the radiation treatment plan, thus generating a beam adjustment signal for adjusting the shape of the beam. However, it is clear from col.16, lines 25-35, that the multileaf collimator is used to dynamically follow the target by changing where the beam is emitted from the collimator as a real time adjustment.

Kanematsu specifically teaches the practice, where a first image signal of the target area is generated, the resulting tracking signal is superimposed on the treatment plan, and the collimator 8 is adjusted in order to change the shape of the beam (radiation field) in order to conform the beam cross section to the deformation of the target during treatment (Fig.5 and col.10, lines 10-29; col.12, line 10 through col.13, line 15). In this way, the target is more accurately irradiated and the surrounding tissues are more accurately avoided.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the device of Kunieda to superimpose the tracking signal on the radiation treatment plan in order to change the shape of the radiation beam in order to realize a more efficient and accurate therapy process, as taught by Kanematsu.

Claims 8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunieda, as applied above against claims 1 and 19, respectively, in view of Hughes (US 6,600,810 B1).

With respect to both claims, Kunieda does not disclose the practice of using a second multileaf collimator.

Hughes teaches the practice of using two multileaf collimators, oriented such that the leaves of the first collimator are not parallel to the second collimator, in order to more precisely control the beam shape (Figs.4 and 5; see at least Title and Abstract). In this way, greater conformity of the beam to the target shape is realized, thus reducing the amount of radiation harming surrounding healthy tissues.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kunieda to use a second multileaf collimator in order to improve beam conformity to the tumor shape and thus reduce the risk of damage to surrounding tissues, as taught by Hughes.

Claims 16, 34, 40 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunieda in view of Depp (US 5,427,097).

With respect to claim 16, Kunieda, as applied to claim 15 above, does not specifically disclose the additional limitation of the practice of moving the source of the radiation beam in order to adjust a projection direction of the radiation beam onto the patient in response to the tracking signal.

Depp specifically teaches such a practice (Fig.1, col.5, lines 10-34), where the gantry that houses the radiation source is moved in response to a tracking signal based upon image data from the tracking sources and detectors in order to keep the radiation beam on target. It is preferable to keep the patient relatively stationary for safety and precautionary reasons, and instead, move the gantry (col.5, lines 32-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kunieda to move the radiation source in response to the tracking signal rather than moving the patient, as taught by Depp, in order to keep the radiation signal on track and to reduce potential harm to the patient.

Regarding claim 34, Kunieda discloses a method for irradiating a target (Figs. 1, 18, 19 and 20), including:

a) establishing a relationship between at least one marker 17 relative to the target (tumor, not referenced in the figures) by measuring a relative position between the at least one marker and the target (col.12, lines 24-42),

b) generating an image signal of the at least one marker,

c) generating a tracking signal in response to the image signal, and

d) adjusting a radiation beam in response to the tracking signal for tracking the target (col.3, lines 14-37), where

e) the target is tracked, as indicated above, while performing IMRT using a first multileaf collimator 15a (col.16, line 33) in which a leaf of the first MLC is adjusted such that a first portion of the target receives more radiation than a second portion of the target.

Kunieda does not specifically disclose the use of internal anatomy of a patient as a marker. Kunieda uses artificial, implanted markers 17 or 14.

Depp specifically teaches the practice of using either existing anatomy, such as a bone, or an implanted marker, depending upon the proximity between the internal anatomy and the target (col.1, lines 50-65). As is known to one skilled in the art, the use of existing anatomy within the patient reduces the need for the invasive surgery of implanting artificial markers, which is not time or cost effective and increases the chance for the patient to become infected in some way.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kunieda to use internal anatomy for the convenience, safety and economics over that of implanting an artificial marker, as taught by Depp.

With respect to claim 40, Kunieda further discloses that the image signal is generated using a camera 21e.

With respect to claim 60, Kunieda, as applied to parent claim 64 above, does not specifically disclose the use of internal anatomy of a patient as a marker. Kunieda uses artificial, implanted markers 17 or 14.

Depp specifically teaches the practice of using either existing anatomy, such as a bone, or an implanted marker, depending upon the proximity between the internal anatomy and the target (col.1, lines 50-65). As is known to one skilled in the art, the use of existing anatomy within the patient reduces the need for the invasive surgery of implanting artificial markers, which is not time or cost effective and increases the chance for the patient to become infected in some way.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kunieda to use internal anatomy for the convenience, safety and economics over that of implanting an artificial marker, as taught by Depp.

Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanematsu in view of Kunieda and in further view of Depp.

Regarding claim 37, Kanematsu discloses a process for irradiating a target (Figs.1, 4 and 5), including:

a) collecting a plurality of images in a same physiological cycle, where the plurality of images provide an indication of a location of the target,

b) create a treatment plan based at least in part on the plurality of images collected at the plurality of phases in the cycle, and

c) delivering a radiation beam to the animal body according to the treatment plan (col.11, lines 35-57), where

d) the radiation beam is delivered to perform IMRT on a target of the animal body in which a first region of the target receives more radiation than a second region of the target while

the target is being tracked, where the target is being tracked and the radiation beam being delivered by adjusting a collimator (col.12, lines 19-40).

Kanematsu does not specifically disclose the use of a multileaf collimator (MLC). However, MLCs are well known and recognized in the practice of IMRT.

Kunieda specifically teaches the practice of using a MLC 15a for performing IMRT (col.16, line 33) and for tracking the target (col.16, lines 28-35), as is known in the art for providing flexible, high-conformance irradiation fields to accurately irradiate the target and spare surrounding healthy tissues.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kanematsu to use an MLC for performing the tracking and IMRT functions, as taught by Kunieda, in order to improve the beam control for accurate treatment, as is known in the art.

With respect to claims 38 and 39, and further regarding claim 37, Kanematsu does not specifically disclose that the images provide an indication of a location of a target relative to an internal marker, either anatomical or implanted. Kanematsu relies on the target itself.

Depp specifically teaches the practice of using either internal anatomy or implanted markers in order to determine the location of a target via automated tracking systems for radiation therapy similar to that of Kanematsu (col.1, lines 50-65). As is known in the art, the use of a marker, such as an implanted marker or nearby bones, provide improved detection reliability since tumors and other diseased tissues are tissues that are similar in attenuation to

benign surrounding tissues. A marker provides sharper contrast, particularly for automated tracking, such that movement is more easily detected.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kanematsu to use either an implanted marker or internal anatomy as taught by Depp in order to more accurately detect and measure motion of a target region of a patient.

Response to Arguments

Applicant's arguments with respect to claims 1, 10, 12, 34, 37 and 64 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas R. Artman whose telephone number is (571) 272-2485. The examiner can normally be reached on 9am - 5:30pm Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas R. Artman
Patent Examiner

EDWARD J. GLICK
SUPERVISORY PATENT EXAMINER